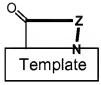
EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Andrea Wilkovich, on July 23, 2010.

The application has been amended as follows:

1. (Currently amended) A compound of the general formula wherein



(I)

is ^{D}Pro-^{L}Pro or ^{L}Pro-^{D}Pro and wherein the amino acid residues in chain Z are:

-P1: Leu; Thr; or Arg;
-P2: Arg; or Trp;
-P3: Leu;
-P4: Lys; hArg [L-homo-arginine]; (BA)G [N-(4-amino-n-butyl)glycine]; or Gln;
-P5: Lys; Gln; hArg; or (PeA)G [N-(5-amino-n-pentyl)glycine];
-P6: Arg, Trp, hArg; (EGU)G [N-(2-guanidinoethyl)glycine]; (EA)G [N-(2-aminoethyl)glycine]; (PrA)G [N-(3-aminopropyl)glycine]; (PeA)G or (BA)G;
-P7: Arg; (PeA)G; or Val;
-P8: Trp; or Bip [L-(4-phenyl)phenylalanine];

-P9: Lys; Arg; or hArg;

-P10: Tyr;

-P11: Arg; or Tyr; and

-P12: Val; or Arg;

with the proviso that

- the amino acid residue in P4 is (BA)G; and/or
- the amino acid residue in P5 is (PeA)G; and/or
- the amino acid residue in P6 is (EGU)G or (EA)G or (PrA)G or (PeA)G or (BA)G; and/or
- the amino acid residue in P7 is (PeA)G.

or an enantiomer thereof or a pharmaceutically acceptable salt thereof.

2-17. (Previously cancelled)

18. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

- P1: Leu;
- P2: Arg;
- P3: Leu;
- P4: Lys;
- P5: Lys;
- P6: (EA)G;
- P7: Arg;
- P8: Trp;
- P9: Lys;
- P10: Tyr;
- P11: Arg; and
- P12: Val.

19. (Previously presented) The compound of formula Ia according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

- P1: Leu;
- P2: Arg;
- P3: Leu;
- P4: hArg;
- P5: hArg;
- P6: (EGU)G;
- P7: Arg;
- P8: Trp;
- P9: hArg;
- P10: Tyr;
- P11: Arg; and
- P12: Val.

20. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

- P1: Leu;
- P2: Arg;
- P3: Leu;
- P4: Lys;
- P5: Lys;
- P6: (PrA)G;
- P7: Arg;
- P8: Trp;
- P9: Lys;
- P10: Tyr;
- P11: Arg; and
- P12: Val.

21. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro; and the amino acid residues in position 1 – 12 are:

- P1: Leu;
- P2: Arg;
- P3: Leu;
- P4: Lys;
- P5: Lys;
- P6: (BA)G;
- P7: Arg;
- P8: Bip;
- P9: Lys;
- P10: Tyr;
- P11: Arg; and
- P12: Val.

22. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

- P1: Leu;
- P2: Arg;
- P3: Leu;
- P4: (BA)G;
- P5: Lys;
- P6: (BA)G;
- P7: Arg;
- P8: Bip;
- P9: Lys;
- P10: Tyr;
- P11: Arg; and
- P12: Val.

23. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

- P1: Leu;
- P2: Arg;
- P3: Leu;
- P4: Lys;
- P5: Lys;
- P6: (PrA)G;
- P7: Arg;
- P8: Bip;
- P9: Lys;
- P10: Tyr;
- P11: Arg; and
- P12: Val.

24. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

- P1: Arg;
- P2: Trp;
- P3: Leu;
- P4: Lys;
- P5: Lys;
- P6: Arg;
- P7: (PeA)G;
- P8: Trp;
- P9: Lys;
- P10: Tyr;
- P11: Tyr; and
- P12: Val.

25. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

P1: Arg;
- P2: Trp;
- P3: Leu;
- P4: Gln;
- P5: (PeA)G;
- P6: Arg;
- P7: Arg;
- P8: Trp;
- P9: Lys;
- P10: Tyr,
- P11: Tyr, and
- P12: Arg.

26. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

P1: Arg;
- P2: Trp;
- P3: Leu;
- P4: Lys;
- P5: (PeA)G;
- P6: Arg;
- P7: Arg;
- P8: Trp;
- P9: Lys;
- P10: Tyr,
- P11: Tyr, and
- P12: Val.

27. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

P1: Thr;
- P2: Trp;
- P3: Leu;
- P4: Lys;
- P5: (PeA)G;
- P6: Arg;
- P7: Arg;
- P8: Trp;
- P9: Lys;
- P10: Tyr;
- P11: Tyr; and

P12: Arg.

28. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

P1: Arg;
- P2: Trp;
- P3: Leu;
- P4: Gln;
- P5: Lys;
- P6: Arg;
- P7: (PeA)G;
- P8: Trp;
- P9: Lys;
- P10: Tyr;
- P11: Tyr; and

P12: Arg.

29. (Previously presented) The compound of formula I according to claim 1 wherein the template is ^{D}Pro-^{L}Pro and the amino acid residues in position 1 – 12 are:

P1: Thr;
- P2: Trp;
- P3: Leu;
- P4: Lys;
- P5: (PcA)G;
- P6: Arg;
- P7: Arg;
- P8: Trp;
- P9: Lys;
- P10: Tyr;
- P11: Tyr, and

P12: Arg.

30. (Cancelled)

31-32. (Previously cancelled)

33. (Previously presented) A pharmaceutical composition containing a compound according to claim 1 and a pharmaceutically inert carrier.

34. (Currently amended) ~~A~~ The composition according to claim 33 in a form suitable for oral, topical, transdermal, injection, buccal, transmucosal, pulmonary or inhalation administration.

35. (Currently amended) ~~A~~ The composition according to claim 33 in form of tablets, dragees, capsules, solutions, liquids, gels, plaster, creams, ointments, syrup, slurries, suspensions, spray, nebuliser or suppositories.

36. (Currently amended) A method for treating ~~or preventing~~ or reducing the risk of bacterial infections ~~or diseases related to such infections, which comprises~~ comprising administering to a patient in need ~~of such treatment or prevention~~ thereof an effective amount of a compound according to claim 1.

37. (Withdrawn) A method for disinfecting or preserving foodstuffs, cosmetics, medicaments and other nutrient-containing materials which comprises adding to such foodstuffs, cosmetics, medicaments and other nutrient-containing materials an effective amount of a compound according to claim 1.

38. (Currently amended) A process for the manufacture of ~~compounds~~ a compound according to claim 1 which process comprises

(a) coupling an appropriately functionalized solid support with an appropriately N-protected derivative of that amino acid which in the desired end-product is in position 5, 6 or 7, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

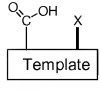
(b) removing the N-protecting group from the product thus obtained;

(c) coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position nearer the N-terminal amino acid residue, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(d) removing the N-protecting group from the product thus obtained;

(e) repeating steps (c) and (d) until the N-terminal amino acid residue has been introduced;

(f) coupling the product thus obtained with a compound of the general formula



II

wherein

is as defined above and X is an N-protecting group or, if

is to be group (a1) or (a2), above, alternatively

(fa) coupling the product obtained in step (e) with an appropriately N-protected derivative of an amino acid of the general formula

HOOC-B-H **III** or HOOC-A-H **IV**

wherein B and A are as defined above , any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(fb) removing the N-protecting group from the product thus obtained; and

(fc) coupling the product thus obtained with an appropriately N-protected derivative of an amino acid of the above general formula IV and, respectively, III, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(g) removing the N-protecting group from the product obtained in step (f) or (fc);

(h) coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is in position 12, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(i) removing the N-protecting group from the product thus obtained;

(j) coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position farther away from position 12, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(k) removing the N-protecting group from the product thus obtained;

(l) repeating steps (j) and (k) until all amino acid residues have been introduced;

(m) if desired, selectively deprotecting one or several protected functional group(s) present in the molecule and appropriately substituting the reactive group(s) thus liberated;

(o) detaching the product thus obtained from the solid support;

(p) cyclizing the product cleaved from the solid support;

(q) if desired, forming one or two interstrand linkage(s) between side-chains of appropriate amino acid residues at opposite positions of the β-strand region;

(r) removing any protecting groups present on functional groups of any members of the chain of amino acid residues and, if desired, any protecting group(s) which may in addition be present in the molecule;

(s) if desired guanidinylating any side-chain amino group present in the chain of amino acid residues; and

(t) if desired, converting the product thus obtained into a pharmaceutically acceptable salt or converting a pharmaceutically acceptable, or unacceptable, salt thus obtained into the corresponding free compound of formula I or into a different, pharmaceutically acceptable, salt.

39. (Currently amended) A process for the manufacture of ~~compounds~~ a compound according to claim 1 which process comprises

(a') coupling an appropriately functionalized solid support with a compound of the general formula

II

wherein

is as defined above and X is an N-protecting group or, if

is to be group (a1) or (a2), above, alternatively

(a'a) coupling said appropriately functionalized solid support with an appropriately N-protected derivative of an amino acid of the general formula

HOOC-B-H **III** or HOOC-A-H **IV**

wherein B and A are as defined above , any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(a'b) removing the N-protecting group from the product thus obtained; and

(a'c) coupling the product thus obtained with an appropriately N-protected derivative of an amino acid of the above general formula IV and, respectively, III, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(b') removing the N-protecting group from the product obtained in step (a') or (a'c);

(c') coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position nearer the N-terminal amino acid residue, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(d') removing the N-protecting group from the product thus obtained;

(e') coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position farther away from position 12, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(f') removing the N-protecting group from the product thus obtained;

(g') repeating steps (e') and (f') until all amino acid residues have been introduced;

(h') if desired, selectively deprotecting one or several protected functional group(s) present in the molecule and appropriately substituting the reactive group(s) thus liberated;

(i') detaching the product thus obtained from the solid support;

(j') cyclizing the product cleaved from the solid support;

(k') if desired forming one or two interstrand linkage(s) between side-chains of appropriate amino acid residues at opposite positions of the β-strand region;

(l') removing any protecting groups present on functional groups of any members of the chain of amino acid residues and, if desired, any protecting group(s) which may in addition be present in the molecule;

(m') if desired guanidinylating any side-chain amino group present in the chain of amino acid residues; and

(n') if desired, converting the product thus obtained into a pharmaceutically acceptable salt or converting a pharmaceutically acceptable, or unacceptable, salt thus obtained into the corresponding free compound of formula I or into a different, pharmaceutically acceptable, salt.

40. (Currently amended) A process for the manufacture of ~~according to claim 38~~ a compound according to claim 1, which process comprises

(a) coupling an appropriately functionalized solid support with an appropriately N-protected derivative of that amino acid which in the desired end-product is in position 5, 6 or 7, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

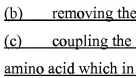
(b) removing the N-protecting group from the product thus obtained;

(c) coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position nearer the N-terminal amino acid residue, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(d) removing the N-protecting group from the product thus obtained;

(e) repeating steps (c) and (d) until the N-terminal amino acid residue has been introduced;

(f) coupling the product thus obtained with a compound of the general formula



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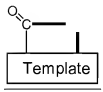
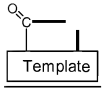
wherein



is as defined above and X is an N-protecting group or, if



is to be group (a1) or (a2), above, alternatively

(fa) coupling the product obtained in step (e) with an appropriately N-protected derivative of an amino acid of the general formula

HOOC-B-H **III** or HOOC-A-H **IV**

wherein B and A are as defined above, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(fb) removing the N-protecting group from the product thus obtained; and

(fc) coupling the product thus obtained with an appropriately N-protected derivative of an amino acid of the above general formula IV and, respectively, III, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(g) removing the N-protecting group from the product obtained in step (f) or (fc);

(h) coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is in position 12, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(i) removing the N-protecting group from the product thus obtained;

(j) coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position farther away from position 12, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(k) removing the N-protecting group from the product thus obtained;

(l) repeating steps (j) and (k) until all amino acid residues have been introduced;

(m) if desired, selectively deprotecting one or several protected functional group(s) present in the molecule and appropriately substituting the reactive group(s) thus liberated;

(o) detaching the product thus obtained from the solid support;

(p) cyclizing the product cleaved from the solid support;

(q) if desired, forming one or two interstrand linkage(s) between side-chains of appropriate amino acid residues at opposite positions of the β-strand region;

(r) removing any protecting groups present on functional groups of any members of the chain of amino acid residues and, if desired, any protecting group(s) which may in addition be present in the molecule;

(s) if desired guanidinylating any side-chain amino group present in the chain of amino acid residues; and

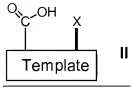
(t) if desired, converting the product thus obtained into a pharmaceutically acceptable salt or converting a pharmaceutically acceptable, or unacceptable, salt thus obtained into the corresponding free compound of formula I or into a different, pharmaceutically acceptable salt, wherein a residue of (BA)G, (PeA)G, (EGU)G, (EA)G or (PrA)G is introduced by coupling with a leaving group-containing agent, followed by nucleophilic displacement with ammonia or guanidine ~~but wherein an amino acid residue of type I or K is introduced by coupling with a leaving group-containing acetylating agent, followed by nucleophilic displacement with an amine of the formula H_2NR^{86} and, respectively, H_2NR^{87} which, if necessary, is appropriately protected~~.

41. (Currently amended) A process according to claim 40 wherein said leaving group-containing ~~acetylating~~ agent is bromo, chloro or iodo acetic acid.

42. (Cancelled)

43. (Currently amended) A process for the manufacture of ~~according to claim 39~~ a compound according to claim 1, which process comprises

(a') coupling an appropriately functionalized solid support with a compound of the general formula



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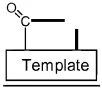
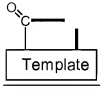
wherein



is as defined above and X is an N-protecting group or, if



is to be group (a1) or (a2), above, alternatively

(a'a) coupling said appropriately functionalized solid support with an appropriately N-protected derivative of an amino acid of the general formula

HOOC-B-H **III** or HOOC-A-H **IV**

wherein B and A are as defined above, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(a'b) removing the N-protecting group from the product thus obtained; and

(a'c) coupling the product thus obtained with an appropriately N-protected derivative of an amino acid of the above general formula IV and, respectively, III, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(b') removing the N-protecting group from the product obtained in step (a') or (a'c);

(c') coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position nearer the N-terminal amino acid residue, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(d') removing the N-protecting group from the product thus obtained;

(e') coupling the product thus obtained with an appropriately N-protected derivative of that amino acid which in the desired end-product is one position farther away from position 12, any functional group which may be present in said N-protected amino acid derivative being likewise appropriately protected;

(f') removing the N-protecting group from the product thus obtained;

(g') repeating steps (e') and (f') until all amino acid residues have been introduced;

(h') if desired, selectively deprotecting one or several protected functional group(s) present in the molecule and appropriately substituting the reactive group(s) thus liberated;

(i') detaching the product thus obtained from the solid support;

(j') cyclizing the product cleaved from the solid support;

(k') if desired forming one or two interstrand linkage(s) between side-chains of appropriate amino acid residues at opposite positions of the β-strand region;

(l') removing any protecting groups present on functional groups of any members of the chain of amino acid residues and, if desired, any protecting group(s) which may in addition be present in the molecule;

(m') if desired guanidinylating any side-chain amino group present in the chain of amino acid residues; and

(n') if desired, converting the product thus obtained into a pharmaceutically acceptable salt or converting a pharmaceutically acceptable, or unacceptable, salt thus obtained into the corresponding free compound of formula I or into a different, pharmaceutically acceptable salt, wherein a residue of (BA)G, (PeA)G, (EGU)G, (EA)G or (PrA)G is introduced by coupling with a leaving group-containing agent, followed by nucleophilic displacement with ammonia or guanidine ~~but wherein an amino acid residue of type I or K is introduced by coupling with a leaving group-containing acetylating agent, followed by nucleophilic displacement with an amine of the formula H_2NR^{86} and, respectively, H_2NR^{87} which, if necessary, is appropriately protected~~.

44. (Currently amended) A process according to claim 43 wherein said leaving group-containing ~~acetylating~~ agent is bromo, chloro or iodo acetic acid.

45. (Cancelled)

46. (Currently amended) A method of treating ~~according to claim 36 wherein said disease is~~ Cystic Fibrosis comprising administering to a patient in need thereof a compound of claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654